REMARKS

Claims 1, 2, and 7-48 are pending and stand rejected in the above-referenced office action. In accordance with the foregoing, claim 20 is amended. Applicant respectfully traverses the rejections and requests a withdrawal of all rejections as set forth below.

Claims 1, 2, and 7-48 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 14-18, 22 and 25-27 Marshall (US Pat. No. 7,191,016). A terminal disclaimer is submitted herewith to overcome the rejection based on the non-statutory double-patenting ground.

Claims 1, 2, 7-10, 16-18, 20-29 and 35-47 stand rejected under 35 U.S.C. 102(b) as being anticipated by Carson (U.S. 5,931,862) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carson (U.S. 5,931,862) in view of Houser (U.S. 6,361,559). Carson fails to teach or suggest the features recited in independent claim 1, including a porous silicone layer or a sheet of collagen fibers formed over the second electrode. The examiner contends Carson discloses a sheet of collagen fibers since the ePTFE sheet will be evenly distributed with perfused collagen. However, the only mention of collagen in Carson is as a pore impregnating material in a gelatin-type wetting procedure. As such, it appears that the collagen may be in a gelatin form for impregnating the pores. Gelatin is an irreversibly hydrolyzed form of collagen in which the fibrous strands separate into globular, random coils. No mention is made of forming a porous sheet of collagen fibers. Alternatively, the examiner relies on Houser for teaching covering electrodes with a porous material such as collagen, to further define a structure incorporating holes, notches, and slots for tissue to shrink and coagulate and to encourage neointimal cell growth. Houser teaches covering an electrode incorporated in a bypass graft and thus has a need to encourage tissue ingrowth. Houser only mentions collagen, fibrinogen, gelatin or urethane for the covering and never mentions a sheet of collagen fibers. Moreover, incorporating holes, notches and slots for tissue to shrink and

coagulate and encourage tissue growth is contradictory to the teachings of Carson. As the examiner states in the last paragraph on page 5, "Carson '862 discloses that the porous layer is adapted to prevent chronic tissue ingrowth" (emphasis added). Carson clearly states "Pore size is chosen small enough to discourage tissue ingrowth" (col. 4, lines 1-3). Carson further states "Unlike in grafts, which require the gelatin to remain in place for two weeks to allow for external tissue growth into the outer surface and for the surface of the lumen to become clotted to minimize bleeding, after the gelatin accomplishes its function to wet out the ePTFE it may be washed away from the surface as it dissolves into the blood. Alternatively, gelatin may expand within the pores of the ePTFE and function to prevent tissue adhesion." (col. 9, 1-9) As such, modifying Carson's covering to a covering as taught by Houser would prevent Carson's lead from functioning as intended since Houser's covering promotes tissue growth while Carson requires that the covering discourage or prevent tissue adhesion or ingrowth. Based on these contradictory teachings and applications, the Applicant respectfully submits it would not be obvious to one having skill in the art to modify the system of Carson with the collagen layer taught by Houser. For at least this reason, Applicant respectfully asserts the rejection of claim 1 and claims 2 and 7-10 dependent thereon based on Carson and Houser is improper and should be withdrawn.

Claim 20 as amended recites "the means for preventing the second electrode from stimulating tissue comprise means for preventing anodal stimulation by the second electrode when the second electrode forms a bipolar pair with the first electrode for stimulation of a heart." The claim amendment is supported, for example, by paragraph 27 of the originally-filed specification which states:

> "the porous layer allows conduction therethrough while preventing direct contact of second electrode 612 with tissue along a wall 663 adjacent apical implant site 162 in order to prevent anodal stimulation of right ventricle 65 when second electrode 612 forms a bipolar pair with first electrode 656 for stimulation of heart left side 680."

Carson discloses a defibrillation electrode covered with a porous plastic that allows defibrillation energy to pass through it. As such, Carson's electrode is intended for delivering stimulation. The examiner's statement that the prevention of chronic tissue ingrowth is a sufficient and effective means of preventing the electrode from stimulating tissue in proximity to the electrode is logically unsupportable. Stimulation energy delivered by a defibrillation electrode will stimulate excitable tissue within the vicinity of the electrode even more effectively when tissue ingrowth, which is typically unexcitable scar tissue, is not present. As such, prevention of tissue ingrowth does not prevent the electrode from stimulating adjacent tissue, but rather make the electrode function more efficiently. Accordingly, Carson does not teach or suggest a second low voltage electrode forming a bipolar pair with a first low voltage electrode and means for preventing anodal stimulation by the second electrode when the second electrode forms a bipolar pair for stimulation of a heart. Applicant respectfully traverses examiner's use of inherency. Carson provides no teaching whatsoever of a control means for preventing the second electrode from stimulating tissue. Houser is silent on the use of a low voltage bipolar pair of electrodes for stimulation of a heart. Applicant respectfully asserts claim 20 is thus allowable and requests withdrawal of the rejection.

Claim 21 relates to an implantable electrical medical system and recites "the porous layer extending over the anode surface allows conduction therethrough and prevents the anode surface from contacting the electrically active tissue in order to prevent anodal stimulation." For the same or similar reasoning as set forth above with regard to claim 20, Carson is insufficient to anticipate claim 21. Claim 21 and claims 22-29 and 35-47 dependent on claim thereon are thus allowable.

Claims 11-15, 30-34 and 48 stand variously rejected under 35 U.S.C. 103(a) as being unpatentable over Carson or Carson in view of Houser in further view of Hull (U.S. 5,269,810) and/or Soukup (U.S. 5,466,252). It is clear that Hull and Soukup fail to compensate for the previously-discussed deficiencies of

Carson and Houser regarding the features set forth in claim 1, from which claims 11-15 depend, and in independent claim 21 from which claims 30-34 depend. Independent claim 48 recites "the porous layer comprising a sheet of collagen fibers wherein the pores are formed by the collagen fibers". None of the additionally cited references teaches or suggests a sheet of collagen fibers formed over an electrode wherein the pores are formed by the collagen fibers. Accordingly, the rejection should be withdrawn.

Claims 1, 2, 7-10, 11, 16, 20-30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall (WO 02/089909 A1) in view of Houser (U.S. 6,361,559). Krall discloses a thin porous ePTFE covering for an implantable electrode, but, as admitted by the examiner, does not expressly disclose that the layer covering the electrode comprises silicone or a sheet of collagen fibers. Houser fails to overcome this deficiency as the teachings of Houser clearly relate to coverings that encourage neointimal cell growth in direct contradiction to Krall's teaching that "the small size of the pores of the exterior surface of the cover provides a barrier to tissue attachment into the electrode." Applicant respectfully asserts it would not be obvious to one having skill in the art to modify Krall's system with the collagen layer as taught by Houser which promotes tissue ingrowth and adhesion since Krall's system would no longer meet the described feature of pore size small enough to substantially preclude cellular penetration. Applicant respectfully submits the rejection of claim 1 and associated dependent claims 2, 7-10, 11, and 16 based on Krall and Houser is improper and should be withdrawn.

With regard to independent claims 20 and 21 and claims 22-30 and 35 dependent on claim 21, Krall fails to teach preventing anodal stimulation by the second electrode. These claims are thus also allowable over the Krall-Houser combination.

Claims 1, 2, 16-24 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belden (U.S. 6,847,845) in view of Houser (U.S. 6,361,559). As admitted by the examiner, Belden does not expressly disclose that the layer

covering the electrode comprises silicone or a sheet of collagen fibers, as in claim 1. As further admitted by the examiner, Belden teaches a porous layer adapted to prevent chronic tissue ingrowth. This teaching is in direct contradiction to the covering disclosed by Houser for encouraging cell growth and bonding between the device and structure. The contradictory teachings of the references do not support a *prima facia* case of obviousness. With regard to independent claims 20 and 21, Belden also fails to teach preventing anodal stimulation by the second electrode. Applicant respectfully asserts the rejection is improper and should be withdrawn.

Applicant respectfully asserts that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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